

# United States Court of Appeals For the First Circuit

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No. 08-1002

IN RE PHARMACEUTICAL INDUSTRY AVERAGE  
WHOLESALE PRICE LITIGATION

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THERESA SHEPLEY; LARRY YOUNG,

Plaintiffs, Appellants,

v.

JOHNSON & JOHNSON; CENTOCOR, INC.;  
ORTHO-BIOTECH PRODUCTS, L.P.,

Defendants, Appellees.

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APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Patti B. Saris, U.S. District Judge]

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Before

Howard, Circuit Judge,  
Zobel\* and Lisi,\*\* District Judges.

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Steve W. Berman, with whom Sean R. Matt, Hagens Berman Sobol Shapiro LLP, Jeffrey Kodroff, John A. Macoretta, Spector, Roseman & Kodroff, P.C., Marc H. Edelson, Hoffman & Edelson, Thomas M. Sobol, Edward Notargiacomo, Hagens Berman Sobol Shapiro LLP, Kenneth A. Wexler, Jennifer Fountain Connolly and Wexler Toriseva

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\*Of the District of Massachusetts, sitting by designation.

\*\*Of the District of Rhode Island, sitting by designation.

Wallace LLP, were on brief for appellants.

Andrew D. Schau, with whom William F. Cavanaugh, Jr., Erik Haas, Adeel A. Mangi and Patterson Belknap Webb & Tyler LLP, were on brief, for appellees.

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September 28, 2009

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**HOWARD, Circuit Judge.** Plaintiffs-Appellants Therese Shepley and Larry Young, representing a class of nationwide consumers, appeal from the district court's adverse entry of a final judgment as to their claims against Defendants-Appellees Johnson & Johnson; Centocor, Inc.; and Ortho Biotech Products, L.P. (collectively "J&J"). The appellants contend that the district court improperly entered judgment against them before trial. For the reasons that follow, we remand this matter to the district court.

## **I. BACKGROUND**

This appeal represents just one case in a sprawling, nationwide multi-district class action involving the pricing of physician-administered pharmaceutical drugs which were reimbursed by Medicare, private insurers and patients making co-insurance payments from 1991 through 2003. The gravamen of the nationwide litigation against the pharmaceutical companies is that they unfairly and deceptively inflated the drugs' "average wholesale prices" ("AWPs"), a price published by the pharmaceutical companies in various private industry publications and widely used as a benchmark for reimbursement payments, while simultaneously offering secret discounts and rebates to physicians. The result of this scheme was that the AWPs dramatically diverged from the physicians' actual acquisition costs, a divergence referred to as the "spread,"

thereby creating a windfall profit for the physicians who bought the drugs at the lower prices but were reimbursed based on the higher prices. The plaintiffs further allege that the pharmaceutical companies exploited this system by "marketing the spread," by which a company used the prospect of windfall profits to induce physicians to prescribe its drug, thereby protecting or increasing market share vis-a-vis competitor drugs. This case involves just a slice of the larger litigation: the claims against J&J by Class 1 plaintiffs -- the group of natural persons nationwide who made co-payments based on AWP for relevant Medicare Part B drugs.<sup>1</sup> For a detailed discussion of this scheme, and of the district court's case management efforts, see In re

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<sup>1</sup>"Class 1: Medicare Part B Co-Payment Class" is defined as:

All natural persons nationwide who made, or who incurred an obligation enforceable at the time of judgment to make, a co-payment based on AWP for a Medicare Part B covered Subject Drug that was manufactured by . . . the Johnson & Johnson Group (Johnson & Johnson, Centocor, Inc., Ortho Biotech, McNeil-PPC, Inc., and Janssen Pharmaceutica Products, L.P.). Excluded from the Class are those who made flat co-payments, who were reimbursed fully for any co-payments, or who have the right to be fully reimbursed; and the residents of the states of Alabama, Alaska, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Montana, and Virginia (where consumer protection statutes do not permit class actions).

In re Pharm. Indus. Average Wholesale Price Litig., 233 F.R.D. 229, 230 (D. Mass. 2006) (footnote omitted).

Pharmaceutical Industry Average Wholesale Price Litigation, No. 08-1056, \_\_\_ F.3d \_\_\_, slip op. (1st Cir. Sept. 2009), and In re Pharmaceutical Industry Average Wholesale Price Litigation, 491 F. Supp. 2d 20 (D. Mass. 2007). This opinion assumes familiarity with those two decisions.

As part of the broader litigation, the district court held a twenty-day bench trial adjudicating the claims of the Class 2 and Class 3 plaintiffs, see In re Pharm. Industry Average Wholesale Price Litig., 233 F.R.D. 229, 231 (D. Mass. 2006) (defining Classes 2 and 3), against a set of pharmaceutical companies, including J&J. See In re Pharm., 491 F. Supp. 2d at 31 ("This bench trial involved two Massachusetts classes. One class, Class 2, consists of third-party payors ('TPPs') in Massachusetts that reimburse Medicare beneficiaries for their statutory twenty percent coinsurance obligations under Medicare, known as Medigap insurance or supplemental insurance. The other class of plaintiffs, Class 3, consists of all third party payors, end-payors, consumers who make coinsurance payments, and consumers who have no insurance for these drugs in Massachusetts and who pay for drugs based on AWP." (footnotes omitted)). In June 2007, the district court entered a split judgment, finding in favor of the Class 2 and 3 plaintiffs as to some of the defendants but not others. Id. at 31-32 (summarizing findings).

J&J was one of the victorious defendants. Although the district court noted that the company's conduct was "at times troubling," it ultimately found that J&J's conduct had not damaged the class because the spread for the two relevant J&J-manufactured drugs, Procrit (epoetin alfa) and Remicade (infliximab), had not substantially exceeded industry expectations about the size of the spread, and therefore J&J's conduct did not rise to the level of egregiousness necessary to trigger liability under Massachusetts General Laws Chapter 93A ("Chapter 93A"). Id. at 31, 103-04. In reaching this conclusion, the district court rejected the Class 2 plaintiffs' contention that any spread at all should trigger potential liability for the defendants (an approach that the court labeled the "per se" liability theory), and instead applied a 30% "speed limit" or "yardstick" for potential liability, whereby only spreads that exceeded 30% would trigger potential liability. The 30% potential liability trigger was also applied to the claims of the Class 3 plaintiffs. Because the spreads for Procrit and Remicade were approximately 30% or less during the class period, the district court declined to find liability as to either Class 2 or Class 3.

On the strength of those findings, during a July 2007 conference relating to the Class 1 plaintiffs' claims against the Bristol Myers Squibb Company (which ultimately settled before trial), the district court characterized its post-trial findings as

having cut off the claims of the Class 1 plaintiffs against J&J. Specifically, the following exchange occurred between the district court and Steve Berman, the attorney representing the Class 1 plaintiffs:

THE COURT: . . . So, there will be no more trials with respect to the first five defendants in Track 1 with respect to, as I understand it, Class 1. . . .

. . . .

MR. BERMAN: There's one issue on Track 1, your Honor.

THE COURT: Yeah?

MR. BERMAN: And, that is Johnson & Johnson. I know that you said that their drugs didn't exceed the 30 percent rule for the purposes of Class 2 and 3. But, it's our position -- and we would like the opportunity to present this or maybe you've already decided -- that the 30 percent would not apply to [Class] 1.

THE COURT: I thought I ruled that. The 30 percent did apply to Track -- to Class 1.

MR. BERMAN: Well, you have a footnote that talks about -- implies that, but you did not rule in that way. That's your ruling, that we have no J & J Class 1 trial.

THE COURT: I thought it was not a footnote. I thought I went on and on about it. I think I went on and on about everything. So, maybe I ought to look at it again.

MR. BERMAN: I don't think you did --

THE COURT: I think I said that I rejected plaintiffs' position that the per se

liability for Class 1 and that I thought that the 30 percent speed limit should apply to Class 1 as well. And, that would be, I thought applicable to all of the defendants.

So why is that not clear?

MR. BERMAN: Well, I didn't see that in your order, your Honor.

THE COURT: They've got it.

MR. BERMAN: At the time we negotiated the -- via that [BMS] settlement, both sides thought that was a risk that could go either way. And, we discussed that with the mediator. The mediator didn't think that it was clear either.

THE COURT: Well --

MR. BERMAN: It's clear now.

THE COURT: It's clear now. And, I will look at it again. If it wasn't clear, it is clear. The 30 percent speed limit applies to Class 1.

I rejected a per se position. And, I have to go look through it again, because I thought it was clear. That's why I essentially had the expert go back and calculate the damages again. Because, the way he did it was he aggregated all the years when he did it with the 30 percent speed limit. He didn't back out the -- it might have been statute of limitations and on the specific [drugs]. That's why I needed a root calculation.

Otherwise, I could have done it. Right? On the per se. Because, he did it year by year.

MR. BERMAN: Correct, you could have, yeah.

THE COURT: I could have done that. I mean . . .



MR. BERMAN: But, we felt it was a different issue with the consumers, because there's no evidence that they had any knowledge of the so-called industry norm of 20, 25 percent.

THE COURT: Well, I ruled to the contrary and I don't accept that position. And, I thought it was clear. If not, I'm making it clear now.

Seizing on this colloquy, J&J began asking the district court to officially seal the fate of the Class 1 plaintiffs' claims: in August 2007, J&J moved for final judgment under Fed. R. Civ. P. 54(b) (allowing the district court to enter final judgment as to "one or more, but fewer than all, claims or parties" in a multi-party or multi-claim lawsuit); the next month, J&J submitted a proposed order concluding that "no reasonable jury could find that the J&J Defendants' conduct violated the consumer protection laws applicable to the Class 1 claims"; and in November 2007, J&J again moved the district court for final judgment, asking it to effect its "stated intention to enter judgment in favor of the J&J Defendants with respect to Class 1" and proposing the same conclusion that "no reasonable jury could find that the J&J Defendants' conduct violated the consumer protection laws applicable to the Class 1 claims."

The Class 1 plaintiffs' responses to these efforts appear to have taken two different positions. In one response, filed by Attorney Donald Haviland, Jr. on behalf of the "Class 1 and Class 3 Consumers," the Class 1 plaintiffs argued that the entry of

judgment against them would "unfairly and inappropriately limit" their right "to adjudicate their claims fully." A separate, later filing by the other attorneys representing the plaintiffs, including Mr. Berman, stated that the "[p]laintiffs . . . neither consent to, nor oppose" the requested relief, but nonetheless argued, inter alia, that the Class 1 plaintiffs' claims had never been adjudicated, and noted that the district court had not made the finding proposed by the Track 1 defendants.<sup>2</sup> The latter filing therefore requested that the Track 1 defendants' proposed finding be omitted from the district court's order.<sup>3</sup>

The district court ultimately entered a final judgment pursuant to Rule 54(b) stating that "the Class 2 and 3 claims against . . . the J&J Defendants . . . proceeded to a bench trial before the Court in November of 2006," and that "[t]he Court . . . dismissed the claims against the J&J Defendants." The order continued:

As to the J&J Defendants, the Court ruled, among other things, that although J&J's conduct was troubling, it did not violate

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<sup>2</sup>The "Track 1" defendants, including J&J, were the first defendants in the multi-district litigation to proceed to trial. See In re Pharm. Industry Average Wholesale Price Litig., 230 F.R.D. 61, 65 n.1 (D. Mass. 2005).

<sup>3</sup>At oral argument before us, counsel for J&J noted that allowing a single class to take two conflicting positions, as the Class 1 plaintiffs arguably have here, has the potential to create unusual, even novel, difficulties. J&J did not press this point at argument or in its brief, however, and therefore we need not explore it here.

Mass. Gen. Laws ch. 93A, in part because the spreads on the J&J Defendants' subject drugs (Procrit® and Remicade®) never substantially exceeded the range of spreads generally expected by the industry and government. [In re Pharm.,] 491 F. Supp. 2d at 104. As a result, the Court ruled that the claims of Class 2 and Class 3 should be dismissed. Id. at 109. The claims by members of Class 1 are dismissed for the same reason.

The order did not include the Track 1 defendants' proposed finding that "no reasonable jury could find that the J&J Defendants' conduct violated the consumer protection laws applicable to the Class 1 claims."

The Class 1 plaintiffs, which include neither industry nor government, appeal.

## **II. STANDARD OF REVIEW**

We begin by noting that the district court's use of the word "dismissed" in its November 2007 order entering judgment, and the fact that it made its findings as to Class 1 after the bench trial involving the Class 2 and 3 plaintiffs, admits of some doubt as to the precise procedural grounding of the judgment. At oral argument, counsel for J&J represented, without objection, that the district court's judgment was entered in accordance with Federal Rule of Civil Procedure 56. The district court, however, made no explicit reference to that Rule, or to summary judgment in general. Although we consider here the consequences of this having been a summary judgment, ultimately we believe the wisest course is to

remand to the district court for further explanation of its ruling and, if necessary, additional proceedings.<sup>4</sup>

We review a grant of summary judgment de novo, drawing all reasonable inferences in favor of the non-moving party. Sullivan v. City of Springfield, 561 F.3d 7, 14 (1st Cir. 2009). "Summary judgment is appropriate where there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Id. (citing Fed. R. Civ. P. 56(c); New Fed Mortgage Corp. v. Nat'l Union Fire Ins. Co. of Pittsburgh, PA, 543 F.3d 7, 11 (1st Cir. 2008)) (internal quotations omitted).

### III. DISCUSSION

On appeal, the appellants argue that the district court erred by extending its findings from the bench trial to extinguish the Class 1 plaintiffs' claims against J&J. It is undisputed that the bench trial adjudicated only claims of Classes 2 and 3, not Class 1. Consequently, it is also undisputed that the Class 1 representative plaintiffs did not participate in the trial. Finally, it is clear from the record that the imposition of that trigger was based on the district court's fact findings as to how

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<sup>4</sup>Application of the Rule 56 rubric makes some sense, in so far as application of Rule 12 would be seemingly impossible under the circumstances, and judgment after trial under Rule 58 would make little sense given that the instant plaintiffs were not part of the trial.

large a spread the Class 2 and Class 3 plaintiffs expected. See generally In re Pharm., 491 F. Supp. 2d 20.

Against this backdrop, the district court's decision to apply its trial findings to impose the 30% potential liability trigger to the Class 1 plaintiffs, leading to entry of judgment as to the Class 1 plaintiffs' claims against J&J, appears problematic. The 30% potential liability trigger, which was derived from the testimony of Dr. Raymond Hartman, represented two sequential decisions by the district court: first, acting as a gatekeeper under Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), the district court admitted Dr. Hartman's testimony about industry expectations into the record evidence; second, acting in its capacity as factfinder, the district court credited that testimony and adopted the 30% potential liability trigger. Both of these decisions were within the power of the district court.

In extending these findings to necessarily encompass the expectations of the Class 1 plaintiffs, however, the district court may have exceeded its power. Unlike the Class 2 and Class 3 plaintiffs, whose claims under Chapter 93A were determined in a bench trial, it is undisputed that the Class 1 plaintiffs were not represented before the court in the previous trial. Additionally, unlike the Class 2 and 3 plaintiffs who all proceeded under Chapter 93A, the Class 1 plaintiffs include members who set forth claims under various state laws, some of which contain jury trial rights.

As a result, while the district court was empowered to find facts as to the former two classes, it had no basis upon which to apply those findings to the latter class.

To enter summary judgment against the Class 1 plaintiffs, the district court would have first had to view the facts in the light most favorable to the plaintiffs as the nonmoving party, see First Marblehead Corp. v. House, 473 F.3d 1, 3 (1st Cir. 2006), which is a very different enterprise from the factfinding engaged in at a bench trial. Rule 56 also requires that the district court conclude that there are no genuine issues as to any material fact. Yet the factfindings at the bench trial as to the Class 2 and Class 3 plaintiffs' expectations regarding the size of the spreads were not made with any deference to the Class 1 plaintiffs' potential evidence, and nothing in the record suggests that the district court applied the deferential standards required by Rule 56 at the July 2007 hearing or when it entered its judgment on the Class 1 plaintiffs' claims against J&J. Moreover, rather than making the necessary finding that there were no genuine issues of material fact, the district court actually deleted language to this effect ("no reasonable jury could find that the J&J Defendants' conduct violated the consumer protection laws applicable to the Class 1 claims") from the defendants' proposed order. The court also found in its June 2007 post-trial order that the issue of what liability trigger to use for Remicade -- an issue that turned on ascertaining

the appropriate industry expectations -- was a "close call," In re Pharm., 491 F. Supp. 2d at 104, thus indicating that, had the court applied the Rule 56 standards, it might well have found there to exist a genuine issue of material fact. For these reasons, entering summary judgment as to the Class 1 plaintiffs' claims against J&J, on the record as we understand it, would have been error.

J&J's arguments to the contrary are unpersuasive. Its contention that the claims of Class 1 were not materially different from the claims of Class 2 and the consumer members of Class 3 says nothing about the different role of the district court in adjudicating those claims in the context of a jury trial. Its characterization of the district court's decision to adopt the 30% potential liability trigger as "legal" (and therefore outside the purview of the jury) fails to account for the fact that the creation of the 30% trigger depended on factual findings relating to the relevant expectations as to the size of spreads. And elsewhere we have rejected J&J's arguments that the district court's adoption of a 30% potential liability trigger was erroneous as a matter of law; those arguments do not provide "alternative grounds" for affirming the district court, as urged by J&J. See In re Pharm., No. 08-1056, \_\_\_ F.3d \_\_\_, slip op.

None of this is to say, however, that the judgment issued by the district court cannot be sustained or that this case must

necessarily proceed to trial on the Class 1 plaintiffs' claims against J&J. If the Rule 54 judgment on the Class 1 claims was intended to address only those claims brought under Ch. 93A, then the judgment seemingly does not reach Class 1 claims arising under other states' consumer protection laws that may provide for trial by jury. Additionally, if the Class 1 plaintiffs have evidence (for example, about relevant expectations with respect to reasonable spreads in the context of the spreads' impact on consumer payments), then the district court ought to have a proffer of such evidence to assist it in deciding whether to grant a properly framed summary judgment motion. As the Class 1 plaintiffs were not participants in the bench trial, the record is lacking with respect to whether the plaintiffs have any such relevant evidence on a material issue. Again, nothing in this opinion should be understood to preclude the district court from entering judgment under Rule 56 on behalf of J&J as to the Class 1 plaintiffs' claims. But if the district court does decide to enter summary judgment, it must do so only after affording the Class 1 plaintiffs the protections to which they are entitled under Rule 56.

#### **IV. CONCLUSION**

Because we lack a clear understanding of both the scope of the district court's judgment and the reasons for the judgment,



we will remand to the district court for additional explanation of its judgment. Although we have considered retaining jurisdiction over the matter, in light of the fact that the district court may find it necessary to take action beyond providing an explanation, we instead **VACATE** and **REMAND**. The parties' rights to appeal are preserved.

No costs are awarded.